PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference XXX	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/IN2004/000142	International filing date *(day/month/year)* 20.05.2004	Priority date *(day/month/year)* 19.03.2004
International Patent Classification (IPC) or national classification and IPC INV. C07H1/06 C07H5/02		
Applicant PHARMED MEDICARE PRIVATE LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 43 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18.10.2005	17.07.2006
Name and mailing address of the International preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer de Nooy, A Telephone No. +31 70 340-2338

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IN2004/000142

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

☒ the international application in the language in which it was filed

☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-23	as originally filed
Claims, Numbers	
1-23	as originally filed
24, 25	received on 03.11.2005 with letter of 18.10.2005
Drawings, Sheets	
1-6	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☒ the description, pages 1-27
- ☒ the claims, Nos. 26-31
- ☒ the drawings, sheets/figs 7,8
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-23
	No:	Claims	24,25
Inventive step (IS)	Yes:	Claims	1-23
	No:	Claims	24,25
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item I
Basis of the report

Amended claims 24 and 25 are considered allowable since in the original description (page 4 lines 9-16, page 23 lines 11-14) it is explicitly stated that the products from the process be amorphous or non-crystalline.
All other amendments however, being page 7 the description of the two extra figures, the extra material of pages 23-26, new claims 26-31 and new figures 7 and 8 are considered not-allowable (Rule 70.2(c) PCT) since in the original application there is no basis for those amendments. There can be no basis for new figures since those figures cannot be exactly the same as a text, therefore, the content of those figures cannot have been present in the original application. The new added pages as well as the new claims 26-31 are also considered to extent the scope of the original application because the addition of particle sizes was not present at all (only one remark, page 23 line 14) where it is stated that the powders have smaller particle size. However, no numbers are specified, therefore, any added number is considered unallowable added matter.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1: P.H. Fairclough et al. Carbohydrate Res. 40 (1975) 285-298
D2: US4380476

Novelty
The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of newly filed claims 24 and 25 is not new in the sense of Article 33(2) PCT.

The documents D1 and D2 disclose the synthesis and isolation of sucralose, thus claims 24 and 25 lack novelty since a product by process must be new and inventive. A product is not rendered novel merely by the fact that it is produced by a new process. Moreover, both D1 and D2 disclose non crystalline sucralose (D1 page 293, sucralose was obtained as a syrup; D2 column 10 line 14 as a syrup) therefore, claims 24 and 25 are considered not

novel.

Inventive step
The present claims 1-23 meet the criteria of Article 33(1) PCT in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claims 1-23, and discloses the synthesis and isolation of sucralose

The subject-matter of claims 1-23 differs from this known subject matter in that a drying step or super critical extraction step as in claim 1 is included. Furthermore, a deacetylation of intermediates of chlorinated sucrose is performed before as well as after said drying step.

The problem to be solved by the present invention may therefore be regarded as the provision of further processes for the synthesis and isolation of sucralose.

The solution proposed in claims 1-23 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons.
It is not obvious for the skilled person to include a drying step as in claim 1 and to perform a deacetylation before as well as after said drying step. In D1 there is no incentive to do so.

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Date
02.08.06

Reference	Application No./Patent No.
	04770659.3 - 2101 PCT/IN2004000142

Applicant/Proprietor
Pharmed Medicare Private Limited

Entry into the European phase before the European Patent Office

These notes describe the procedural steps required for entry into the European phase before the European Patent Office (EPO). You are advised to read them carefully: failure to take the necessary action in time can lead to your application being deemed withdrawn.

1. The above-mentioned international patent application has been given European application No. **04770659.3**.

2. Applicants **without** a residence or their principal place of business in an EPC contracting state may themselves initiate European processing of their international applications, provided they do so before expiry of the 31st month from the priority date (see also point 6 below).

   During the European phase before the EPO as designated or elected Office, however, such applicants must be represented by a professional representative (Arts. 133(2) and 134(1), (7) EPC).

   Procedural acts performed after expiry of the 31st month by a professional representative who acted during the international phase but is not authorised to act before the EPO have no legal effect and therefore lead to loss of rights.

   Please note that a professional representative authorised to act before the EPO and who acted for the applicant during the international phase does not automatically become the representative for the European phase. Applicants are therefore strongly advised to appoint in good time any representative they wish to initiate the European phase for them; otherwise, the EPO has to send all communications direct to the applicant.

3. Applicants **with** a residence or their principal place of business in an EPC contracting state are not obliged to appoint, for the European phase before the EPO as designated or elected Office, a professional representative authorised to act before the EPO.
   However, in view of the complexity of the procedure it is recommended that they do so.

4. Applicants and professional representatives are also strongly advised to initiate the European phase using EPO Form 1200 (available free of charge from the EPO). This however is not compulsory.

5. **To enter the European phase before the EPO**, the following acts must be performed.
(N.B.: Failure validly to do so will entail loss of rights or other adverse legal consequences.)

5.1 If the EPO is acting as **designated** or **elected** Office (Arts. 22(1)(3) and 39(1) PCT respectively), applicants must, within 31 months from the date of filing or (where applicable) the earliest priority date:

a) Supply a translation of the international application into an EPO official language, if the International Bureau did not publish the application in such a language (Art. 22(1) PCT and R. 107(1)(a) EPC).
If the translation is not filed in time, the international application is deemed withdrawn before the EPO (R. 108(1) EPC).
This loss of rights is deemed not to have occurred if the translation is then filed within a two-month grace period as from notification of an EPO communication, provided a surcharge is paid at the same time (R. 108(3) EPC).

b) Pay the national basic fee (EUR 170,00) and, where a supplementary European search report has to be drawn up, the search fee (EUR 720,00 ; R. 107(1)(c) and (e) EPC).

c) If the time limit under Article 79(2) EPC expires before the 31-month time limit, pay the designation fee (EUR 80,00) for each contracting state designated (R. 107(1)(d) EPC).

d) If the time limit under Article 94(2) EPC expires before the 31-month time limit, file the written request for examination **and** pay the examination fee (EUR 1490,00 ; R. 107(1)(f) EPC).

e) Pay the third-year renewal fee (EUR 400,00) if it falls due before expiry of the 31-month time limit (R. 107(1)(g) EPC).

If the fees under (b) to (d) above are not paid in time, or the written request for examination is not filed in time, the international application is deemed withdrawn before the EPO, or the contracting-state designation(s) in question is (are) deemed withdrawn (R. 108(1) and (2) EPC). However, the fees may still be validly paid within a two-month grace period as from notification of an EPO communication, provided the necessary surcharges are paid at the same time (R. 108(3) EPC). For the renewal fee under (e) above, the grace period is **six** months from the fee's due date (Art. 86(2) EPC).

For an overview of search and examination fees, see OJ EPO 11/2005, 577 and 03/2006.

5.2 If the application documents on which the European grant procedure is to be based comprise more then ten claims, a claims fee is payable within the 31-month time limit under Rule 107(1) EPC for the eleventh and each subsequent claim (R. 110(1) EPC). The fee can however still be paid within a one-month grace period as from notification of an EPO communication pointing out the failure to pay (R. 110(2) EPC).

6. If the applicant had a representative during the application's international phase, the present notes will be sent to the representative, asking him to inform the applicant accordingly.

All subsequent communications will be sent to the applicant, or - if the EPO is informed of his appointment in time - to the applicant's European representative.

7. For more details about time limits and procedural acts before the EPO as designated and elected Office, see the EPO brochure

   How to get a European patent
   Guide for applicants - Part 2
   PCT procedure before the EPO - "Euro-PCT"

   This brochure, the list of professional representatives before the EPO, Form 1200 and details of the latest fees are now all available on the Internet under

   http://www.european-patent-office.org

Receiving section

Europäisches Patentamt • European Patent Office • Office européen des brevets

ABSTRACT

Present invention relates to disclosure of application of some innovative techniques useful for substantially improving process efficiency of production of chlorinated sucrose including their intermediates and derivatives. Application of mild methods of drying has been made for recovery of chlorinated sucrose or their intermediates and derivatives, in substantially pure form or with other solid chemical impurities, obtained at various stages in the process of production of chlorinated sucrose. Mild methods of drying included agitated thin film drying, spray drying, freeze drying and super critical extraction. Use of alkoxides has been introduced for deacylation instead of alkali hydroxides or alkaline earth hydroxides. Deacylation has been shown to be effective both, either before or after drying of the reaction mixture. Extraction and purification of desired products i.e. of chlorinated sucrose or its intermediates or derivatives, from dried solid mixtures could be achieved by using appropriate extraction method, including but not limited to solvent extraction and super critical extraction. Further purification of such extracts can be done by crystallization or direct drying under mild conditions.